DR. KARELLAS: Andrew Karellas. We heard comments about the importance of the medical audit, and there is no question about that. And we all understand, and we all know that this is an extremely critical part. And this is not the medical audit versus the physical evaluation, or the physics work, or the technologist's work. There is valuable time spent on that part, but I don't think it's because we do not have the answers from the medical audit. It's not because we don't have the time. It's because we cannot come up with a solution.

There is time available, but it is very difficult to find a good way of doing it. And I would like to remind us that as important as the medical audit is, and all these issues with radiologists and perception, and they are critical issues, if the technologist does not deliver you a good image, and if you do not have an effective quality assurance program, you will not have anything of much value at the end of the pipeline for the radiologist to review. And that's very important to remember. It is good to streamline certain operations from the technical end,

recordkeeping procedures, physics, technologists, and we all agree. In fact, many technologists and physicists agree in the streamlining part, but that's still a very critical part of the whole process.

CHAIRPERSON HARVEY: And you have to acknowledge it's difficult to maintain a high standard day after day. There's so many pressures, there's so many patients, so much to be done. People are cutting back. Mammography faces a lot of issues of this nature that make the day by day activities more difficult. Any other comments on other alternatives, or other ideas? Well, we've had some really excellent ideas, and we've all been listening carefully to them. And hopefully, the FDA people have been also, because it's not easy to make any changes.

Everything is a balance. I was explaining this as a force forward for those of you who may have had physics a long time ago, when I did. Everything is balanced. You have different weights and different pressures on mammography, and we've come to some particular equilibrium. Now if we want to switch, there will need to be some negotiations as to where

that equilibrium will be found. And some people are moving towards digital very rapidly, but we have many, many small rural facilities that won't see anything like digital unless there's some breakthrough that makes them much less expensive, and people buy their piece of equipment and they keep it. And it will last for quite some time, particularly in some of the smaller facilities where it doesn't have the burden of heavy use. So it will be quite a long time, I think, before that viewbox is dusty in some of the more rural towns. Ms. Martin, did you have something?

MS. MARTIN: Well, I'd just like to follow-up on the lady from Missouri that spoke about viewboxes. If there's anything else that is currently being covered by the ACR program but it's obviously voluntary as opposed to mandated, the viewbox conditions probably have the greatest effect on what is visualized out there. If there's anything that's going to be picked up at all, if we could incorporate some viewbox requirements - the viewing conditions are all over the place.

CHAIRPERSON HARVEY: Yes. Dr. Karellas.

DR. KARELLAS: Andrew Karellas. I totally agree with that. If inspectors were testing viewboxes, they would find quite a few incidents of non-compliance. It's a significant issue. And, in fact, from my point of view, as much as I don't like inspectors going in and inspecting everything physically, I don't think it's a bad thing to go to one randomly and test and say well, this is not in compliance. And I think they will probably be ahead of the physicists and technologists on occasion, because if the physicist there is once a year or twice a year, you are not going to catch that very easily.

CHAIRPERSON HARVEY: Excellent. I think we'll have a break. We'll be back in about 10 minutes. Thank you.

(Whereupon, the proceedings in the above-entitled matter went off the record at 2:43 p.m. and went back on the record at 2:58 p.m.)

CHAIRPERSON HARVEY: On the record. Our next section has to do with the use of digitized film screen mammograms and compressed FFDM digital data. I believe we have a speaker, Mr. Robert Phillips.

Welcome.

DR. PHILLIPS: Thank you. Good morning or afternoon now. When Charlie Finder asked me to do this talk, he described a little bit of what he wanted. I apologize. The title is a little bit different, but it will get to the same point. If I tell you something you already know, I apologize. If I don't cover something that I should, please ask questions and we'll get something done.

I want to talk today about medical device regulation of PACS devices. That includes digitizers and compression schemes and all sorts of things like that. By the way, if you don't know me, I'm Chief of the Radiological Devices Branch. I'm in the Office of Device Evaluation. Our job is to approve new medical devices under the Medical Device Law.

Let me outline what I want to talk about first; the process of device classification. Then I want to go on to various market clearance processes, what we did to the PACS, the classification regulation of PACS, and then discuss some of the issues with compression, then on to digitizers, then full field

digital mammography approvals. Hopefully I can do that in about 15 minutes. Then you can ask me lots of questions afterwards.

Device classification is founded in the Medical Device Amendments which were passed in 1976. Since then, the amendments have been revised several times but still basic to it is all devices that were on the market prior to 1976 were grandfathered. These grandfathered devices were placed into three classifications. This was done on a device category basis with the assistance of an advisory panel. Most of it was done back in the late seventies and early eighties.

The device classification system created three classes. The first class was general controls. These are things like GMPs, good manufacturing practices, submitting 510(k)s, having a recall or a malfunction file, things like that, basically low risk devices. Since then, the amendments to the Food, Drug, and Cosmetic Act have resulted in most of these devices being exempt from submission of 510(k) which I'll get to in a little bit.

Class 2 devices are one step up. They are devices that need general controls and special controls in order to assure their safety and effectiveness. There, originally, the special controls were standards. But the process for developing standards was very complex such that essentially none were promulgated.

What happened instead is Congress came back and changed it from standards to special controls. These now allow the use of voluntary standards - a company can use those - other processes which again assure safety and effectiveness.

The last category was for the devices that were most critical in terms of safety and effectiveness; implants, life-sustaining, and any device that could not be shown safe and effective since 1976, some device that's been on the market. For these, a PMA is necessary. I'll get to PMAs in a moment.

The 510(k) process primarily applies to Class 1 and 2. It applies to some pre-amendments Class 3 devices, but most of those at this point we

have asked for PMAs for so that's dropping away. The basis of a 510(k) clearance is the new device is shown to be substantially equivalent to a device that's already on the market. Originally, it was substantially equivalent to a device that was on the market prior to 1976. But by extension, that was changed to any device that's already being marketed.

It is essentially a need-to process. The manufacturer of the new device shows that his device is substantially equivalent to the old device. This does not mean it is identical. It means it's substantially or in the most part equivalent. One of the derivatives of this is that the new device is no more safe or effective than the old device that was on the market.

If someone came in tomorrow and wanted to market an old flat-plate fluoroscope, we would have no legal basis for not approving it under the Medical Device Laws. I doubt that they would sell many of them, but that just gives you the background.

In the 510(k) process, technology creep can occur. Again, the device is not identical. It's

substantially equivalent. As changes are made, a whole series of minor changes can be made. At some point, you look back and say, "Gosh, the new device I'm looking at is really not the same as the original device was on the market." But that's just recognized as being part of the process.

In the 510(k) process, there's no requirement for the new device to be better than the old device. That means that the 510(k) process will not improve the breed, if you will. The device again need only be as safe and effective as the predicate device. Just for numbers, we clear about 4,000 510(k)s per year. That's over about five or six different medical specialty areas.

The PMA process is different. In this process, the device is shown to be safe and effective. It's no longer substantially equivalent. It is safe and effective on its own right. The device is not judged in comparison to any other device, only on its own characteristics. Full field digital mammography has been going through the PMA process. I'll explain that a little bit later.

The Center approves about 35 to 50 pre-market approvals or PMAs per year. As a benchmark, when we are estimating our time, we estimate it takes a reviewer about a week to do a 510(k). A PMA accounts for about one-half person year. That's generally a team review over a multitude of various specialties.

PACS is a device that was classified about 15 years ago with the rest of our radiological devices. At the time we were looking at PACS, it was determined that it was a pre-amendments device. There were devices that could be called PACS or image reviewing-type systems that were on the market prior to 1976. These were analog. Since then, it's all converted over to digital but the concept was the same.

We looked at these. We divided the hardware up into five different categories. The first was the PACS workstation itself. This is the thing that you use in your practice. It's the business end of the process. It includes the CRTs, the software, and it's the PACS device that allows you to manipulate

the image, change the contrast, change the gray scale range, enhancement if you want, all sorts of things like that.

Communications were the second device. These are the things like modems and transmission lines and things like that. Data storage devices were the third. These would be magnetic disks, CDS, large optical disks, any sort of process that's used for storing digital data.

The next was the hard-copy output devices. I heard someone earlier talking about printers. Printers are the major product here. Then the last item that we looked at was digitizers. These are devices which can take an analog or continuous tone-type image and convert it into a digital array that represents that image.

The communications and storage devices were put into Class 1. They are exempt from 510(k) submission. That means that the manufacturer does not have to come to the agency to put one of these on the market. There are still other requirements such as records and good manufacturing practices and things

like that that apply.

But our thinking when we did this was that the communications technology and the storage technology is really dominated by the computer industry and not by the medical device community. What has happened in that area is far beyond our ability to influence it.

Hard copy, digitizer, and PACS workstations were placed into Class 2. In this case, a 510(k) submission is necessary. We felt the device operation here was critical to the diagnostic process so that issues of safety and effectiveness were present. Up to now, most of these devices have been marketed with a general claim, that is, they can be used to, let's say, manipulate radiographic images.

Let's go into compression for a minute. We have two types of compression that we're concerned about. One is called lossy compression. The other is non-lossy compression. In non-lossy compression, the data is to be restored so that it is essentially identical to the original whereas with non-lossy compression, there is a loss of information that is

irrecoverable.

When we were working on this originally about 15 years ago, a standard then was that about a four to one compression ratio was about the maximum you could go without starting to lose significant data. With the advent of some of the newer techniques such as the JPEG 2000 technique, that ratio has gone up. Now I'm told you can have compression ratios up to 40 to one without significant loss of information.

Unfortunately, there is very sparse literature in the medical libraries on what it means to have lossy compression. No one that I'm aware of has gone and done a series where they had different degrees of data loss and determined what the final diagnostic outcomes were. So that's a big unknown right now. As I indicate here, compression greater than four to one in the past was a big deal.

When we approve or clear devices that were involved using lossy compression, we require that at the point that the lossy compression was applied all derivative images, whether they were looked at either on a soft copy like a CRT or on a hard copy like a

printed version, would have to have some sort of annotation attached indicating that the image had undergone lossy compression. That way, anybody looking at that film would know that they were not looking at a complete original data set. That is continued up to now.

Newer technologies are coming along quite rapidly. The newest standard for compression is currently called JPEG 2000. It uses a process called wavelets which I won't go into. But as I indicated, some of the other newer technologies can allow some very, very high compressions. Again, these usages are pretty much general claims. We have not cleared any lossy compression device for use with mammography that I'm aware of.

What you might be unaware of though is that in using public transmission lines and other things - and this was more applicable to analog images than to digital - many of the public transmission lines, the telephone company and so on, use their own compression audit rhythms to maximize the use of the band spread in their signal communication systems.

When you are using public transmission systems, there's a potential for compression to be hidden in the transmission process itself.

This is just an example of what compression looks like. (Indicating.) This is an original photograph. This is the same photograph using the old standard, JPEG, after reconstruction from 40 to one compression. You can see you have lost a significant amount of detail. The image is blocky. There is a distinct loss of acuity for the whole image. I won't say any more.

Here is the same image using the JPEG 2000 restored from 40 to one compression. If you compare the two images, you can see they are pretty close. They are not perfect. If you go up and look at this carefully, you will see there is still some fuzziness that's introduced and so on. But it certainly is a major improvement from the old JPEG which is this image here. This will be made available in the proceedings of this meeting. If you have an interest in compression references, here are a few that we have put together. As I say, they will be made available.

Digitizers, as I indicated, are also Class 2 device. They are used to convert a conventional image into a digital image. The primary usage has been in radiography for allowing old analog images, continuous tone images, what you see on your X-ray that you put up on the screen, allowing them to be put into a digital database for future manipulation.

They are also used as a precursor to some CAD devices. Again, all the CAD devices work on a digital basis not on an analog basis so that prior to using one of the CAD devices, the first step is to take your X-ray and digitize it. They are cleared with the general indication for use.

Again, to my knowledge, we have not cleared any for specifically mammographic use. I'll have a caveat there, except for the CAD devices where you are not working with an original data set where you are going to do a diagnosis. If you recall, for our CAD devices, the labeling says that the first thing you do is your normal diagnosis of the film and then use the CAD devices to help you almost as a second reader.

Full field digital mammography has been on the market now since about 1997 or so. It's been very interesting for us. First of all, there's no consensus on what technology is being used or going to be used for digital mammography. That creates one of the problems in trying to develop for MQSA a QC program because each system at this time is essentially unique so that the QC programs have to be developed for each specific system.

We originally tried to clear these devices under the 510(k) process but were unable to establish the substantial equivalents between the digital films and the continuous tone analog films primarily because the inter- and intra-reader variability was so high that in order to get statistical significance, you would have to have study populations of tens of thousands of patients. The result was that the three devices had been approved under the PMA program which allows us to prove something based on its own safety and effectiveness rather than by comparison to something that's already on the market.

Again, as I commented, the MQSA QC is

based on the individual testing provided by the sponsor. We as yet do not have any general approach for quality control. Charlie, that's about the end of it. I'm available for questions.

CHAIRPERSON HARVEY: Questions from the Committee? Ms. Martin.

MS. MARTIN: Is it your department that will be setting the standards, if any, for monitors that are to be used for mammography for PACS systems?

DR. PHILLIPS: We approve monitors but for PACS system, probably yes. There's a lot of work going on right now trying to figure out what's good, what's bad, or what's good for mammography, what's not good for mammography. We have tried to set the benchmark at five megapixels and above for mammography use.

MS. MARTIN: And with that, is your department going to establish the testing procedures or are you going to follow a lot of what's in the AAPM task group reports? In other words, where is this correlation going to happen for the physicist and the testing that will be done on these monitors and the

standards? In other words, what do we judge them against?

DR. PHILLIPS: The AAPM is not a standard setting organization. What they do is provide standards of practice for their membership. We have been asking them for a long time to try and change that because a lot of what they are doing is very useful, as you just indicated.

We would work with AAPM. We would work with NEMA. We would work with the various scientific organizations. We have members that sit on various standards and international standards organizations. That is probably the mechanism that we'll use to develop some sort of standard. We'll work with, let's say, an IEC standards group. When they promulgate a standard, if it meets our needs, we would then endorse it and it becomes usable in the 510(k) process.

CHAIRPERSON HARVEY: Dr. Karellas.

DR. KARELLAS: Andrew Karellas. Do you have a set of requirements or do you envision a set of requirements that somebody could submit to you for doing lossy compression for digital mammograms?

That's the number one question. Two is, would that have to be done separately for different data sets from different manufacturers?

DR. PHILLIPS: I don't know about the different data sets. At this point, no, we do not have a set of requirements. We honestly don't even know what to evaluate when you are talking about that. If someone wanted to come in with a lossy compression process for mammography, first of all, we have to work with Dr. Finder on this because it affects MQSA also. But most likely, it would end up being a rather large clinical study where you would assess the clinical outcome versus the degree of data loss. I don't see that as being a really simple study to do yet.

DR. KARELLAS: Thank you.

CHAIRPERSON HARVEY: Any other questions?

MS. MARTIN: I have one more question. I guess maybe I'm missing something here. So at this point, there are no specifications or any monitors that are permitted to be used for mammography interpretation other than those that are sold and integrated basically with the three manufacturer

systems. Assuming that is the case, do you have any time frame as to when that will change?

DR. PHILLIPS: No, I didn't say there were no monitors. There are monitors that we have approved for mammography use.

MS. MARTIN: Okay.

DR. PHILLIPS: We're using right now the category of five megapixel and above. Plus, we asked for a whole slew. There's an IEC standard on monitors. We're asking for that data to be calculated out and provided to us.

MS. MARTIN: Okay.

DR. PHILLIPS: Digitizers and lossy compression are the areas where we have not had any mammographic use.

MS. MARTIN: Is this the question then? My question came up a while ago about whether the digitized films are going to be accepted or is that later?

DR. FINDER: If you are done asking Dr. Phillips questions, we're going to get started with the discussion right now if that's okay.

DR. PHILLIPS: Lead on.

DR. FINDER: So with Dr. Phillips' presentation and the early public speakers' presentations as background, we're going to be asking the Committee to discuss the use of digital data compression in order to reduce the size of full field digital mammo files, in order to make storage of images in PACS more economical, and also the use for transmission of images to remote reading sites feasible. There's also increasing interest in the mammographic community in digitizing screen film images so that they can be stored electronically and transmitted also for remote reading.

We're going to be asking the Committee to discuss some of these issues that I'm going to talk about right now and whatever else they come up with; the risks and benefits of allowing such practices, how such practices could affect the quality of the images being evaluated and the ultimate clinical outcomes, how such digital data could impact the performance of adjunct devices such as computer-aided detection and computer-aided diagnosis devices, and then getting

back to a more fundamental question of, what methods can FDA and the public be assured that such practices ensure adequate image quality?

So one of the issues that we're talking about is, how can FDA take a compression algorithm, take a digitizer and say without having to go through huge clinical trials that this will ensure adequate safety and effectiveness? You have a half hour. I'm sure you can come up with the hard answers in that period of time.

(Laughter.)

DR. FINDER: Actually, if you want to take less, that's also okay. Fifteen minutes would be fine too.

MS. MARTIN: I just asked the question. I didn't ask the answer it.

(Laughter.)

CHAIRPERSON HARVEY: She shouldn't have to answer her own question, right?

DR. FINDER: Do any of the Committee Members have any questions before we begin? You don't have a lot of time. Let me just give you some

examples on some of the issues that have come up. People are asking us questions. When it comes to digitizers, two of the main ones are the following.

I want to take my film screen mammogram, put it in a digitizer, and then I want to store the film in that electronic format. I want to destroy the original. That's one issue. Another one that's come in is, I want to do the exact same thing but I'm going to keep the original someplace or I'm going to give it to the patient and let them keep it. Is that okay when I use my electronic version next year when I compare it against the original at that time?

The other is, I want to digitize this image and send it some place else to be read, the original interpretation at some remote site. Another factor on that one is, I'm going to send it someplace else. It's going to be read somewhere else. But it's also going to go through a CAD device.

How is all this going to impact? What's acceptable? What isn't? Those are the questions that if would you start dealing with that right now for the digitizer and spend a little time on that, then we'll

get into some more of the questions about compression which is a whole other issue.

DR. RAMOS: Yes, I am not a radiologist but just looking at the images that Dr. Phillips presented, I think that compression seems like a big deal. When you compare the images, obviously there is some data that is lost during the transition. Definitely I believe that someone, somewhere needs to keep the original of the digital image.

I think that the place that it may have more possibilities should be the institution. The moment that you put it somewhere else, you are losing something. There are possibilities there for losing some data. Just access all the time is a big issue. I don't believe that a lot of patients, a lot of facilities are going to have access to have the equipment that is going to be able to reproduce these images.

CHAIRPERSON HARVEY: Maryanne Harvey, I don't see how people can make decisions about this unless they do a study, a clinical trial. Otherwise, all you are doing is putting out your own biases or

thoughts on the matter. You need to have something more analytical I would say in order to do that. How can we find a way for some organization to support a study to see whether or not data is lost?

DR. KARELLAS: Andrew Karellas, we have been conducting a study in the past year or so. It's very preliminary and relatively narrow. But we have used human observers, radiologists, and also what is called numerical-type observers which is a mathematical calculation. We are finding some preliminary and very interesting aspects of image compression.

(1) Image compression today is not what it used to be ten years ago. The technology is advancing very fast. (2) We were surprised in that very limited set of data that you can actually compress mammographic images with simulated lesions to a great extent, meaning that perhaps you can do calcifications at a ten to one compression and masses up to 20 to one compression.

The statistical results showed equivalents. Again, the study has not been published

yet. So the validity of the study will have some weight when it is peer-reviewed and published. But the work has more or less been completed. But it addresses a very narrow part of the spectrum. I believe that other investigators will be looking into that. But it is not going to be anytime soon.

We checked very carefully to see who else is doing work in this area. Initially, we thought there would be a lot of people who had done a lot of work. There is much literature on image compression but not on digital mammography and not on patient-related imagery.

So you have all these mathematical papers out there, but as far as we know, there is very little that can give us the information that we need that we can say, "This is our recommendation that we want to make. There are these studies out there, four or five very high quality peer-reviewed papers. There appears to be a trend that it is safe to accept a certain level of compression." That of course may not include reversible, non-lossy compression. That might be a relatively easy decision to make if we are assured

that there will be no loss of data.

DR. FINDER: Basically, to update you on what our guidance tries to say, we have accepted lossless or non-lossy compression in these areas. We have said, as long as you are not into the lossy field, we feel it's okay. And you are, from what I have been able to gather, able to get compression ratios of about three to four to one, in which, when you reconstitute that data, it is exactly the same as the original.

You cannot tell the difference. You can compare pixel by pixel, number by number. It's exactly the same. If we had some time, we could go into how there are certain mechanisms to do that. Some of them are fairly simple to understand because even I understood it when they explained it to me, being a radiologist.

(Laughter.)

DR. FINDER: So there are methods to do that. It's when we get into this lossy area that these issues become problematic because the data and the studies don't really seem to be there. At this

point, the question really is, for the uses that we're talking about - and there are various uses - one I think you can consider as counting this data, either the compressed data or the digitized data as the original.

If it's used for primary interpretation, should there be a certain requirement for that? Is there a lesser requirement if it's going to be used for a comparison of next year? But it won't be used for the original interpretation because that was read the year before. Another thing is, is there some kind of standard that we might consider for cases in which the images are sent to the referring physician who won't be doing really an interpretation but will be using this either to judge where the lesion is after it's been shown to them? Can there be these varying levels?

I will say that at least in terms of our regulations and the Act, when we're talking about at least the primary interpretation, we're saying the original film. That's probably the highest standard that we have to be careful about. And I'm not sure

that we really can make a distinction under our regulations or the Act when we're talking about comparison films because again our standard right now is the films and film screen systems have to be maintained for five or ten years so that comparisons can be done off of those originals.

We don't allow a facility to send a copy to another facility to be interpreted. We say they have to release the originals. So maybe those two were actually the same. But then there's the third one which is sending it to either referring physicians or patients or whatever for non-primary interpretation purposes. So there may be different levels. But certainly at the highest one, we're talking about the original.

DR. PHILLIPS: I just want to point out that you may be asking a question that you might not have to answer as time progresses, that is, how to address lossy compression. As I indicated and as you indicated, ten to 15 years ago, four to one was the limit for lossless compression.

With the newer algorithms that are being

used, that number is going up, whereas the JPEG 2000, somewhere between ten and 40 is still considered lossy. That's a tremendous improvement in the database that you're trying to transmit and saves you a significant amount of time both in storage space and transmission time. So wait two years, you might not have to answer the question.

CHAIRPERSON HARVEY: We'd like that.

(Laughter.)

DR. MARSHALL: Hi. My name is Julian Marshall. I'm from R2 Technology, a CAD provider. By way of background, currently our customers are scanning about eight million cases per year, 32 million sheets of film. We quite frequently get asked, "Why can't I save all of this work that I'm doing scanning these films and use them for something useful in the future?"

There are several things that they would like to do. They would like to get out of the quandary that they are placed in when they read digital mammography of having to put the prior mammogram on the lightbox orthogonal to their rather

dim monitors and 11,000 NIT lightbox and get out of this blast in the eyes to look at the priors, go back to the dim monitors and look at the images.

But if they can take a digitized film and put it up on the workstation, they can now do a much more spatially-related, temporal comparison between prior and current. I guarantee you they will prefer that reading environment.

Second of all, regarding film digitizers, they are not all the same. Just because they carry a 510(k) approval doesn't mean that a radiologist would like the look of the mammogram that comes out of it. That's really noticed in a few different ways. Some of the digitizers exhibit what we call fixed pattern noise.

If you stretch the contrast up on the image that comes out of a digitizer, you see regular, geometric patterns completely unrelated to the original image itself that come from motor noise and other things. Scanners are electromechanical devices. They are prone to all the foibles of analog electronics.

In addition, if you look around the skin line on a mammogram, you will notice inability of the scanner to penetrate the film near the skin line. As manufacturers come out with films that are darker and darker, the problem gets worse and worse. So radiologists are going to have to get actively involved in evaluating the images that come out of digitizing systems to determine if it gives them the information that they want in the digital image.

Now, as it turns out, most of the people scanning films and thinking about future use of them are not thinking about, "I want somebody across the street to read that image in soft copy," although there are some applications of that. Most often they are thinking, "Next year, I want to go back and look to that image."

I think that gives you a very different set of goals. So if you consider that separately, when you digitize a relevant prior for display, you are largely not concerned with resolution anymore because you are not concerned about the morphology of little calcifications. Now, you are concerned about

the number of them. Has the number increased from the prior?

You are not necessarily concerned about the skin line because you still have the original image for your current examination there. That's where you are looking at the skin line. I think for the most part that digitized priors are going to be acceptable for soft copy reading in clinical practice.

Our company currently has several clinical studies going on in Europe investigating these very things, 100 micron digitization not 50 microns that we do normally for CAD purposes and so on. So those will be interesting results when they come out. I think that's it.

CHAIRPERSON HARVEY: Thank you.

DR. FINDER: Dr. Finder, I have a question. Do you know - and I don't know if you want to answer this question - what the effect of putting compressed data into your system would be?

DR. MARSHALL: The images that were shown of Lena - that's that woman's name by the way - if you look to the 40 to one JPEG 2000 compressed image, what

you noticed was largely the gestalt view. The picture looked much the same. But if you go and look in detail around the edge of the hat, you see paisley or some shape.

CAD algorithms internally divide largely into two things; looking for mass lesions, large structures, spiculations, lines, and so on and microcalcifications. One of the keys in distinguishing microcalcifications is the morphology of the microcalcification. Well, if you compression algorithm begins to add little paisley shapes, mandlebrot sort of looking things, it will impact the ability for the CAD algorithm to distinguish between one type of calcification and another.

Now, that's not to say that over time CAD algorithms couldn't develop insensitivity to that by training on enough cases that are one way or another way. The problem is that for the compression algorithms some are standardized - the JPEG 2000 kind are standardized - some are not.

There are a lot of companies out there with very clever mathematicians creating very clever

compression schemes that all do different things and leave different droppings in the images in different ways. The danger is that if images go through a proprietary compression algorithm, become uncompressed with damage left over, are then fed to a CAD algorithm, I don't believe the CAD vendors would probably guarantee the results that one would get from that process.

DR. FINDER: Thank you. Other questions?

CHAIRPERSON HARVEY: Dr. Karellas.

DR. KARELLAS: Andrew Karellas, I don't have a question. CAD is secondary although a very potentially important part at least of the whole screening process. But images may be viewed initially, go through CAD, interpreted, uncompressed. I believe that the compression schemes are best, at least in the next three years, for storage and communication.

Now, there is an exception to that. Of course, if you store them for a later time, the CAD becomes less important than the primary interpretation. However, if you do transmit the

images for the CAD to be applied at a central facility, then that is a concern because the moment you transmit the images and they are compressed for the transmission part and then they want to use the CAD on the other side, then the issue that you are raising is of course value.

CHAIRPERSON HARVEY: Yes.

DR. REICHER: Murray Reicher. Hopefully these comments can be beneficial in clarifying. It seems like we're discussing two different things. One is digitizing. One is compression. We're tending to mix the two. Both processes have the potential to change an image.

Separating the topic of digitizing for a moment, the gentleman from R2 here and other vendors have been digitizing mammograms for quite a long time and have shown that their technology at least is able to detect even a single microcalcification with a digitized image. That's an uncompressed image.

So to that degree, we have millions of data points showing that one can digitize an image with a certain vendor's digitizer. Depending on

whether you talk to R2 or ICAD or CADx or whoever it is, it will be a different one. And that image is reproduced faithfully enough that it can undergo computer analysis and see even a single calc.

So there's been quite a bit of testing on, is a digitized image equal to the original image? It's not identical. It can't ever be identical. But it seems like there's a lot of data showing that it's very close to identical.

There was a comment made about monitors. I just wanted to give the FDA something to reflect on. When the American College of Radiology ten years ago started writing standards for digital imaging, they came up with a monitor standard. I was on a committee a couple of years later. Everybody was kind of embarrassed when they realized that we came up with a monitor standard that was not resolution defined.

So there really needs to be a resolution standard. I think it's in the interest of the FDA and the general public to have a requirement that says that the image should be displayed at its full resolution at some point in the reading process and

that the software should promote that concept and that the rest should be, in my view, monitor independent.

If you look at all of the FDA cleared manufacturers' websites for high resolution monitors today, by irony, all of them have at least four mammograms up on each screen meaning that we're talking about data compression having a five or ten percent effect. Well, I would contend that a very high percentage - and I have observed a lot of them - of people today reading digital mammography may be displaying as little as one in four to one in 16 pixels at the time of display because of multi-formatting.

So the monitor itself is irrelevant. What's relevant is something on that image that says it's being displayed at full resolution and something in the software that makes that happen easily. Furthermore, I think there's at least one vendor already that has a monitor independent software solution that's been cleared by the FDA where they provide a software-only PACS solution. The hospital IT department can buy any monitor they want to. I

don't know if that slipped through or was cognitively put through.

With regard to data compression, it also seems like we're talking about multiple topics. I have at least a dozen years experience with data compression. I'm not a physicist, but my understanding is that lossy versus lossless is mathematically defined but that there's another threshold of data compression that is mathematically lossless but visually non-lossless.

The image is identical. Original data can't be recreated. That may impact whether or not CAD can be used. But if the image has not changed, I think it's important that we have at least a common nomenclature to decide what that is. There's lossless. There's visually nondestructive. There's visually destructive.

There actually is a fair amount of non-mammography literature on visually nondestructive data compression that far exceeds, at least is two to three times what you can get with lossy data compression. That data is in human chest X-rays and generally

accepted that you can go eight to ten to one without any radiologist or any machine for that matter really being able to detect a significant difference in the image.

The example at 40 to one between JPEG 2000 and JPEG that was shown is a great example. But it has the potential to be misleading because I think the experience has shown that whereas JPEG 2000 creates blurriness and good old JPEG creates blockiness, both have about the identical threshold before they start degrading images. With regard to mammography, blurriness may be worse than blockiness.

So what I'm saying is, probably JPEG and JPEG 2000 don't differ in terms of what the actual number is. It's probably going to be somewhere between eight and ten to one before images start to change slightly.

So I think what colors all of my comments this week is that how the FDA acts and how the public's point of view is formulated depends on whether we enter this stage of time feeling like we have mammography being done pretty well and we have to

be very careful before we make any types of changes that could potentially screw things up, or whether we believe we have a national mammography crisis where four out of five days a week a woman may come in and have a mammogram read with 50 percent or less of the optimal sensitivity and we have to do something about it. Those are my last comments, I promise.

(Laughter.)

CHAIRPERSON HARVEY: Thank you. Yes, Dr. Karellas.

DR. KARELLAS: Andrew Karellas, just very quickly. Yes, as Dr. Reichert mentioned, there is a lot of literature on data compression and a lot of it in image compression and quite a significant body of image compression for chest and other modalities over the past 15 or 20 years. There is no question about that.

We do not have much on mammography. We have even less on digital mammography. So we just do not have enough data for digital mammography at this point. This may not mean that we have to wait for five or six years before any decisions are made. It

is possible to look into the literature for other examinations or modalities and try to derive certain conclusions and put together emerging data on digital mammography. But right now, we do not have much.

CHAIRPERSON HARVEY: Yes.

DR. MARSHALL: Julian Marshall of R2 again. One comment back on the earlier statement you made Dr. Karellas on compressing microcalcifications at ten to one and masses at 40 to one. That's fine and good as long as you know in fact where the calcs are and you know where the masses are. You really can't even rely on CAD algorithms to tell you that because it's not an exact science. So how one would make the determination of how to compress which part of the image would be interesting I think.

I wanted to just mention briefly we have always taken a very conservative view on compression. Until recently, we did no compression at all for the simple reason that I think our customers are not ready to go to compression. If you talk to mammographers, they are very concerned about the fineness and the detail and the minutia of the images and the accuracy

of what they are looking at, the quality of the images and so on.

So we internally have not done any compression at all. We are now beginning to, as Bob Phillips alluded to, do compression on transmission. That means the images get lossless compressed as they are transmitted and they are reexpanded at the other end. But it has no impact on the actual pixel data whatsoever. That's just a normal part of DICOM and medical imaging every day. But other than that, I don't foresee us using any lossless compression at all for years to come.

One cautionary note on storing mammograms in your PACS with any sort of lossy compression. One thing that's coming down the road for CAD - maybe not very quickly but it's coming - will be the time when CAD algorithms begin to look at temporal change. So the CAD algorithm will look at the current mammogram, look at the prior mammogram, and say this is different than that. If you introduce compression artifacts to the priors, you may not have the advantage of being able to do that. So that's one cautionary note.

DR. KARELLAS: Andrew Karellas, yes, I totally agree. The compression at 32 on for masses and much less than that for calcifications is a hypothesis. I'm not aware of any data or at least we do not have any data that indicates that it's safe to do that with clinical images.

All we have done is extremely limited under relatively narrow conditions. All we are seeing is that this is a very interesting area to explore because we feel that if we can break through these barriers some years from now, some years from now, we might be able to use image compression to our advantage.

DR. FINDER: Just trying to move things along, I do have a specific question that we received. I just wanted to get the Committee's opinion on it. In the situation where a facility decides to digitize film screen image and only use it for specific purposes such as for comparison for next year or for use with referring physicians and they are going to keep the original - so the original is going to be somewhere and it may not be in their files but with

the patient - would that be acceptable or do we worry about the fact that if they are going to be using it for comparisons we're letting the cat out of the bag already at that point? Is anybody concerned about that?

MS. MARTIN: I'm not concerned. That's exactly the scenario I got asked to bring here because that's what they are wanting to do. That's exactly what they are wanting to do. Like the gentleman said, you don't want those bright lights and the dim monitors.

CHAIRPERSON HARVEY: Dr. Karellas.

DR. KARELLAS: Andrew Karellas, however, provided when they do that, they do it in the proper way. While Dr. Phillips mentioned that they are FDA approved devices, I believe it was not for mammography other than CAD. But it has to be done in a proper way. I would be concerned about digitizing film in a poor fashion.

Although the film is stored, it's not really being used and you may be using the poorer quality. But if it is done very well and there are

certain good guidelines for doing it and there is compliance with the guidelines, perhaps it may be an acceptable way of doing it.

DR. FINDER: Well, I would say that none of these units as far as I know have been sold for that purpose and have been cleared for that purpose. So we run into certain issues about, if we approve it for use like this when it hasn't been approved for sale, there are issues there also.

CHAIRPERSON HARVEY: Yes.

DR. THOMAS: Jerry Thomas, I have looked very critically at all digitizers but not in terms of mammography. I'll share a couple of comments. A Dmax runs around 3.5. If you have a mammography image with a Dmax greater than 3.5, you are going to lose that information. It will not digitize. Dmin is around two and a quarter, probably 0.25 on those. Not two and a quarter, I'm going the wrong direction here.

DR. FINDER: Would you just explain that you are talking about density?

DR. THOMAS: Yes, okay, the optical density range that it will digitize, its dynamic range

ranges from 0.25 to 3.5 on the ones that I have looked at. The technical design of them are such that you are not going to see a substantial shift. If it shifts, it's going to shift the entire range so the minimum optical density is going to be higher than 0.25 if the Dmax digitized goes higher. I don't not believe that any of the digitizers can go above about 3.7, if that high.

The second thing that was mentioned by Julian is very important, that is, in the black, there is an incredible amount of noise in most of the CDC-based digitizers. There's been a lot of improvements in the last few years, but it's still very noisy. I just came from teaching a course this past Saturday in your part of the world. I was asked this question by about 15 technologists. When can we start digitizing our existing screen film?

That's important in terms of the transition from screen film to digital interpretation. At this point in time, we're going to have substantial numbers of missed cancers and diseases looking at soft copy disk play where I have an illuminator sitting

next to it because of the bright light that's coming from the illuminator and the failure of the radiologist to be able to adjust between two different luminance levels from those viewing devices.

For general mammography though, I'll finish by saying that our CAD companies have proven the effectiveness of film digitization. Their algorithms are very sensitive. The average luminance within a mammography image until we get to the skin line falls within the capabilities of the digitizers.

So it makes perfect sense within certain guidelines and regulations or I should say within certain digitization standards in terms of the performance standards of the device to allow something like that to happen. But one has to be very critical in terms of the dynamic range as well as what the noise is within the blacks. Thank you.

CHAIRPERSON HARVEY: Thank you. Any more comments? Do you have what you need, Dr. Finder?

DR. FINDER: Yes.

CHAIRPERSON HARVEY: Thank you. Thank you to everyone who contributed to that discussion. Dr.

Barr has a few statistics that I asked her to gather earlier in my concern for our ability to meet capacity needs into the future.

DR. BARR: Helen Barr, FDA, first of all, while I am up here giving you these, I wanted to take the opportunity which I didn't do earlier to thank everyone on the Committee for his or her time. I know that you are all busy people with responsibilities elsewhere. On behalf of the agency, I want to tell you how much your time is appreciated. I'll give you these statistics. Then I want to pose one question to Dr. Finder. That will just give him a few minutes to worry while I give you these statistics.

DR. FINDER: You don't have to ask the question here. We can talk about it back in the office.

(Laughter.)

DR. BARR: No, we have to talk about it here. I gave you the statistic that as of April 1, 2004 there were 9,079 mammography facilities. Maryanne Harvey asked me if I could reiterate what the trend in that has been over the years. Then I'll give

you the units.

In October 2000, we had 9,933, October 2001, 9,558, October 2002, 9,306, and October 2003, 9,114. The units is a little more difficult for me to tell you about. I'm just going to actually give you the last time we did the units in November '03 and I'll tell you why. First of all, I told you that on April 1 - or I didn't get a chance to tell you this but Maryanne asked me - to compare with that 9,079 facilities, there were 13,643 units or an average of about 1.5 units per facility. In November '03 to correlate with that 9,123 facilities, there were 13,632 units.

The reason I'm not going to go further back in the units is in November we changed how we looked and counted the units. We used to count inspected units. Then we said to ourselves, "Well, if we're really looking at capacity - and people want to know the units these days really because of capacity access issues - that we should really count all units out there that are in service, have been accredited and are in service but perhaps haven't been inspected

yet."

So that's why. Going back, it's going to look like we had a big jump in units when we actually changed the way we looked at them. So we can go on from last November.

Charlie, the one question I wanted to pose to you, which is for own my learning purposes and for the Committee, something that came up today was about the viewboxes. Now, I can't imagine that the original people who dealt with MQSA regs when they were being developed just totally forgot about viewboxes. You know me, I love to go back in history and see.

Assuming we must have made a conscious decision before to leave viewbox out of the regulations, I just wonder if you could bring us up to speed on what some of the stumbling blocks were or reasons were, not that I don't want to go back and visit things. Then before you answer that, I just wanted to say one thing so I can go sit down while you answer.

You asked about stereotactic. Dr. Finder and I have discussed that we will add a future NMQAAC

meeting. I can't promise it will be the next one but adding a NMQAAC meeting in the future will give people the opportunity to talk about stereotactic and their thoughts on that. Okay, go ahead.

DR. FINDER: Regarding viewboxes, it wasn't forgotten about. It was discussed. They were talking about a lot of issues at the time including checking the eyesight of the individual radiologists. I'm not kidding. That was part of it because you are talking about visual acuity and everything else.

The problem was that there wasn't full agreement on what the standards should be and how you should check against them. At that time, there was the big issue about, should you be reading on a dedicated memo viewbox with higher light levels than the standard viewbox? There was no consensus on that. In fact, some of the data seemed to show later that maybe because of this issue about the light hitting your eyes, you actually might be making your problems even worse by having these high intensity viewboxes.

We did however address some of it. We did say that facilities were required to have masking

materials available to address the issue of the extraneous light coming from the viewbox and that all facilities had to have hotlights available. But we didn't get into the specifics of how often they were supposed to be cleaned or what the luminescence had to be or any of those specific issues because at the time we weren't able to come up with a requirement that could adequately be tested and inspected against.

It's certainly something to consider. The ACR has guidelines about what they believe are recommendations for that. But we didn't put it in a regulation at the time. It's certainly something we can consider again. But if we're done with that, I did want to get into some of these guidance questions which address some of the issues that we talked about earlier that I know are of some interest.

I do want to mention the fact that for those who aren't aware we have put all our guidance into what's called the Policy Guidance Help System which is available on the Internet. The last time I looked, if you typed out all of the pages, it's somewhere around five to six hundred or so pages. We

are in the process of actually going through that entire mass of information and updating it.

I was hoping to be able to present at least some of that here at the time, but it hasn't gone through the full clearance process yet. It's still working its way through the system. So maybe at the next meeting we'll be able to talk a little bit more about it. But I do have a couple of specific questions that have come up and wanted the Committee's opinion on.

One of them, clairvoyantly I must admit, was this business about scanning paper records, QC records, and personnel documents so that they could be used for inspections or whatever purpose the facility had. We were talking about scanning in the QC records, the mammography equipment evaluations, the annual physics surveys, all the personnel documentation, all the paper records in effect.

Then they could be used either transmitted back and forth between a central site for the inspection of the facility or the facility could use them just at a single site. The question that we were

really having is, I don't think anybody has any issue about scanning those documents in and using them for various purposes. One of the issues though that we did try and come up with or had a concern about was, does the facility have to maintain at least some of these records in hard copy, original form?

I just wanted to try and get the Committee's idea about records that are generated by the facility itself. So those would basically be the QC records, issues like that. Is there a feeling that those QC tests that were done by the facility's technologist, should they be maintained in their original format?

The reason I bring that up is for the very small chance that there is an issue later on about falsification of records. There are ways to determine whether a record has been falsified if you have the original versus you lose some of that if it becomes scanned in or copied like that. Any thoughts?

DR. KARELLAS: Andrew Karellas, if a facility has both digital and paper, it defeats the purpose of streamlining the operation. There may be

certain documents that for one reason or another cannot be scanned. That's particularly the case with QC films that we do, phantom images, collimation assessment, that you save them. That one can be saved as a hard copy.

But if we start saving processor records and certificates of attendance, I think that we're defeating the whole purpose. I believe somebody can falsify a certificate of attendance perhaps just as easily as they can falsify any other document.

DR. FINDER: Yes, we weren't talking about keeping a hard copy of CME certificates or anything like that because they were an original to the facility anyhow. The only thing we were talking about, if anything, was to save the original paper, like charts for the QC records that were generated at the facility if that's felt to be important.

I would also add that our feeling was that the facility would still have to be able to at least generate a hard copy if the inspector needed it for documentation purposes and things like that. But yes, our feeling is to try and move as much as we can into

the electronic world.

MS. RIGSBY: Amy Rigsby, I hate to say this but if somebody is going to cheat, it doesn't matter how perfect or how wonderful the system is. They are going to cheat somehow if they are going to. I don't know if that should be a consideration or not. If they are going to, they are going to.

CHAIRPERSON HARVEY: Ms. Martin.

MS. MARTIN: The only thing I can think of to add is to highly recommend that they back it up so that they don't have a single copy on hard disk of their QC records.

CHAIRPERSON HARVEY: Whoops, there goes the month.

MS. MARTIN: Yes.

DR. FINDER: That actually is a very good point because the number of citations might go up quite significantly as soon as the power spikes.

(Laughter.)

MS. MANN: Are some places out there already doing their QC electronically? Then they would just have to print it to have a printed record.

So it probably would make sense for them to just leave it electronic.

DR. FINDER: Right.

MS. MARTIN: The Kodak system is electronic. We have facilities that have been totally electronic for a couple of years now at least with all their QC. They just print it out as needed if the inspector wants a copy. They have no paper copies.

DR. FINDER: Right, and we would address that issue in guidance by saying that those records that are electronically generated would be that. They wouldn't have to necessarily print them out unless the inspector needed to make a copy for whatever reason.

CHAIRPERSON HARVEY: Dr. Ramos.

DR. RAMOS: Yes, Catalina Ramos. This is a question. If you have the original record in hard copy but you are going to move it electronically, does it have any HIPAA implications that you need to request?

DR. FINDER: This is Dr. Finder. None of these records are patient records.

DR. RAMOS: Okay.

DR. FINDER: It's QC records so as far as I can tell, there is no HIPAA issue.

CHAIRPERSON HARVEY: Ms. Martin.

MS. MARTIN: I really highly recommend they actually scan it in. We had a facility that lost nine months of their QC records when their QC tech got mad and left and took all of the QC data with her. So actually it would have been much to the benefit of the facility if they had a scanned copy of that QC data.

CHAIRPERSON HARVEY: Unless she erased the program.

DR. FINDER: I think now instead they are going to walk off with the laptop.

CHAIRPERSON HARVEY: That's right.

(Laughter.)

DR. FINDER: So I'm not sure it's going to help much. Another question that we have gotten recently. As you are well aware under our regulations in the law, patients are required to be sent lay summaries, summaries of their results from their mammograms. We recently got a request from a facility where the patients specifically do not want to be sent

the lay summary.

Our question is, how do we handle that situation? Do we want to go against the patient's specific request? Do we want to have the facility go against that request? If we don't, what type of measures do we require or should we require to ensure that this won't be abused by facilities that really just don't want to send them out and they are going to convince their patients not to ask for them or something like that? Has anybody else heard of this issue?

MS. MOUNT: Carol Mount, we have had the same situation. It's not frequent, but the patient just does not want that letter sent to her home. So we will manually pull it out and deliver it via interclinic mail to her physician who will then hand it to her. But it's very infrequent that it happens.

DR. FINDER: We have a slightly different situation where the patient specifically states she doesn't want to get it at all. She doesn't want it sent. She doesn't want to receive it. Should we tell the facility that they are not to honor the patient's

request or what?

DR. HARRISON: Miles Harrison, we have had similar situations to that and we have done it the same way. In that particular case, that lay record goes along with the technical report and my office chart. So you have satisfied both sides of it. You did not send a report to a person who didn't want it. The report still exists and is discoverable.

DR. FINDER: All right, and do you happen to know if the facility had the patient sign anything specific to that request to indicate that or no?

DR. HARRISON: Again, I'm the surgeon and not the radiologist. As far as I know, I have not been made privy to any signature in the radiology department that released them.

CHAIRPERSON HARVEY: Dr. Timins.

DR. TIMINS: Julie Timins, I would imagine you would need the patient to sign a release for that.

MS. PURA: Linda Pura, you could have the patient sign the release, but I would recommend that in your documentation somewhere that you write in there that this was explained to the patient and this

was the outcome and then have whoever did the explanation sign that off.

DR. FINDER: Okay, any other comments? All right, another quick question. It's a quick question. I don't know how quick the answer is. We had a number of issues that have come up with small field digital mammography. These are digital image receptors that were basically originally designed for use in interventional, but they can also be used in some standard mammographic units for diagnostic work.

But because of their size, you cannot do a full mammogram. You are only looking at a small portion of the breast. Therefore, these can only be used for diagnostic-type work. So in the past, what we have done is we have said that these small receptors do not require their own accreditation. They are used as part of an otherwise accredited unit. They don't have to go through a separate accreditation because there's no clinical image review for these things.

We have also said that these receptors, if they are going to be used for diagnostic work, would

have had to have already gotten clearance from the FDA's Office of Device Evaluation so that in their clearance it states that they can be used for diagnostic work. A lot of them in the beginning were only approved for interventional-type studies.

However, we now come up to the question, should we include small field digital as some subsegment of full field digital in terms of personnel qualifications, in the sense that, should we be requesting that people who use these units get some type of training in digital, the eight hours of initial training? Leave it at that. Should they?

CHAIRPERSON HARVEY: Ms. Martin.

MS. MARTIN: I know those units that he's talking about. It's a very different set up than a full field digital. I think somehow they do need to go through the manufacturer's training, and yet obviously if the technologist that goes through the training today leaves tomorrow.

My facilities certainly have not had eight hours of the equivalent of full field digital to use those little diagnostic units. They may have had an

hour extra from the in-service from the manufacturer. But they are basically following the QC program from the manufacturer and that would be the extent of it. And I felt comfortable with that.

CHAIRPERSON HARVEY: Any other experience?

MS. MOUNT: Carol Mount, just throwing a question out, when techs are trained stereo, they record those credits. That's basically the same thing only it's upright as opposed to prone.

DR. FINDER: I guess the issue is, if we include it as part of a mammographic modality, we can require some type of training. If we say it's somewhere in the limbo, it's nowhere, we can't do anything in terms of requiring any type of training. It always becomes an issue of, where does this fit in? In the past, we have left it moot. But we're getting more and more questions about this. The question is, do we address it and how do we address it?

CHAIRPERSON HARVEY: Dr. Karellas.

DR. KARELLAS: Andrew Karellas, some of these devices can produce very good image quality. On occasion, having the right device can be very useful

because they have very small pixel size. So radiologists are often very high on using those for calcifications because you can see it very well.

However, it does raise the potential for overexposure here because being digital you can crank the exposure up. The more you give, the better the quality of the image. So that does raise a red flag. People must be trained to use digital. I would not recommend people who are used to doing just the film screening go on to the digital receptor without any training for that.

DR. FINDER: Is that the general consensus of the Committee?

CHAIRPERSON HARVEY: Yes, I think.

DR. FINDER: Okay, well, just to go on that a little bit more, would you say that if somebody who had already gotten eight hours of FFDM training that that would count toward the small field digital?

DR. KARELLAS: I would think that would be fair. The one concern I have is with automatic exposure control because I would have to know exactly how every one of these devices operates. If it is

purely in the manual mode, that means that you can give any exposure you want. I do not know the specifics about every single of these devices. But I think it's fair to say that if you have all the requirements for the digital, that would be adequate, perhaps barely adequate, for the small field.

DR. FINDER: What about the following situation? These small field digital receptors have been around for a large number of years. Any consideration to grandfathering in people who have been using them for a long period of time?

MS. MARTIN: I wouldn't have a problem with that because I know all my facilities that have been using them. We have technique charts posted for these small field receptors. We measure the dose on the small field receptors with the phantom. So your physicist has checked it out. There's a posted technique chart. They have received manufacturers training. I don't see why we wouldn't allow them to go ahead and use them.

DR. HARRISON: And these have been available for many years. It would seem to me we're

just simply trying to document that indeed the technologist had their baseline training. That would be inclusive it sounds like to me.

MS. MOUNT: Carol Mount, I would see grandfathering them in. It's just my gut feeling and it's just my opinion, but I don't think we're going to see a lot more of those out there with full field digital out there. I think people are going to buy that instead. So to grandfather in the current ones would be a good idea.

DR. FINDER: Those were the questions that I had.

CHAIRPERSON HARVEY: Excellent. We have come to the last item on our agenda today which is the review and approval of the summary minutes from our previous meeting which was last April 2003. It seems like just yesterday. Does anyone have any recommendations, changes, and/or other comments they wanted to make about the previous minutes? If not, I would entertain a motion to approve them.

MS. MARTIN: So moved.

CHAIRPERSON HARVEY: May I have a second?

DR. KARELLAS: Second.

CHAIRPERSON HARVEY: Second, all right, excellent. The next item has to do with future meetings. Dr. Finder.

DR. FINDER: Well, I remember last year at this time I was saying the exact same thing. We expected to have a meeting in the fall. It didn't quite work out that way this time. But we do expect to have another meeting in the fall. Probably what we're going to be talking about is a further continuation of some of the issues that may pop up with reauthorization because that still is an ongoing process. That would be my expectation.

The other thing is, as I mentioned, we are working on revising the guidance. Some of the questions that I just spoke with you about here will probably be incorporated into a future guidance document. If we have to go through the entire Policy Guidance Help System and revise that, we may be talking about a huge document which may take up a lot of time to go over but it may be a topic of discussion at that meeting.

We are lucky in one sense that the people who are here are actually going to be on the Committee in the fall. So does anybody have any specific times when they would like or can't make, if they know that ahead of time, if there are any big meetings coming up or anything like that? Obviously what's going to happen when we get down to the nitty gritty of it, the details, I'll send out, like I did the last time, a fax or email asking for your availability. But if you know at this point that there are going to be some issues, we might as well find that out right now.

DR. TIMINS: I won't be around the first three weeks of October.

DR. FINDER: October.

DR. HARRISON: I want to know when the Redskins are in town.

DR. FINDER: Yes, we do usually get requests for when Redskins games are and also the nice weather. Look, I tried my best this time.

CHAIRPERSON HARVEY: You did a good job.

DR. FINDER: I missed cherry blossoms by a little bit, but you can't ask for everything.

Usually the first week or so in October is always bad because you never know if the government is going to be funded at that time. So we try and stay away from that. We either try and get it in September or later on in October or early November. I try and keep it from getting too far into the winter because we have had snowfalls and things like that which make traveling problematic.

CHAIRPERSON HARVEY: Then will we have the minutes to get to.

DR. FINDER: Yes, in terms of the minutes of this meeting, we will be sharing those with the Institute of Medicine. I'll be happy to pass along everything that we have said here. They will also have the transcript. I'm sure they are going to be talking to us and maybe individual Committee Members if they care to. So I would assume we're going to be talking about some time in the fall. I will send out additional information when it becomes available.

CHAIRPERSON HARVEY: Excellent. Any other comments from any members? Thank you for coming and for a productive meeting. This meeting is adjourned.

Off the record.

(Whereupon, the above-entitled matter concluded at 4:25 p.m.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: National Mammography Quality Assurance Advisory Committee

Before: DHHS/PHS/FDA/CDRH

Date: April 19, 2004

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.